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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/010,283 | 11/13/2001 | Carl-Axel Bauer | 06275-150003 | 5064 |

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| EXAMINER | |
|---|---|
| KIM, JENNIFER M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

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| 08/07/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/010,283 | BAUER ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Kim | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *May 20, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *9,11-17 and 21-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11-17 and 21-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

6/2/08, 6/27/08; 7/14/08

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submission filed on May 20, 2008 has been entered.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 9, 11-17 and 21-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record in view of Roberts et al. Thorax 49 (11): pages 1090-1095 (1994) of record.

3. Carling et al. on the abstract, page 1, lines 7-15, page 2, lines 10-37, page 4, lines 23-29, page 7-9 (examples), and page 10 (claims), teach a medicament containing effective amounts of formoterol (b2-agonist, bronchodilator) and budesonide (steroid) in combination for simultaneous, sequential or separate administration by inhalation in treatment of severe asthma and other respiratory disorder with effective amounts within Applicants' ranges set forth in claims. Carling et al. teach that the combination comprising formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but the combination also has a rapid onset of action and this new feature is of utmost importance in order to establish a higher compliance for patients and it provides a rescue medicine thereby avoiding the necessity for the patient of carrying two different inhalers. (page 4, lines 4-10). Carling et al. teach that the combination of formoterol and budesonide in a single formulation simplifies life for patients considerably and makes life more comfortable and secure in treating respiratory disorder such as asthma. (page 4, lines 10-12, lines 23-29).

Carling et al. do not expressly teach the treatment of COPD.

Roberts et al. teach that bronchodilators and inhaled steroids, as anti-asthma drugs, alone or together were prescribed to patients with asthma, COPD and bronchitis. (page 1092, the data in Table I, Results). Roberts et al. teach that of the 1605 patients diagnosed with COPD, 727 (equivalent to 45.3%) were prescribed both an inhaled steroid and an inhaled bronchodilator. (page 1092, under results). Roberts et al. teach that the prescribed bronchodilator included b2 agonist, and the inhaled steroids were beclomethasone or budesonide. (page 1091, second paragraph).

It would have been obvious to skilled artisan to employ the Carling's medicament comprising formoterol and budesonide (b2-agonist, bronchodilator and inhaled steroid) in reducing the frequency and/or intensity of COPD since COPD and asthma are routinely treated and prescribed with inhaled steroids (budesonide) and b2 agonist having bronchodilating effects as taught by Roberts et al. One of ordinary skilled in the art would have been motivated to employ Carling's medicament in reducing the severity or intensity or frequency of having COPD with reasonable expectation of success since each of the active agents utilized in Carling's medicament are prescribed to treat a patient with both asthmatics and COPD as taught by Roberts et al. Further, Carling et al's combination not only has a greater efficacy and duration of bronchodilating action but it establishes a higher compliance because it is conveniently in a single inhaler.

Applicants' declaration has been carefully reviewed and reconsidered. However, it is not found to be persuasive because Robert et al. teach that the respiratory conditions such as COPD and asthma are routinely treated and prescribed with inhaled steroids (budesonide) and bronchodilator having b2 agonistic activity such as formoterol. Further, Carling et al's combination comprising budesonide and formoterol has a greater efficacy and duration of bronchodilation action. Therefore, the greater efficacy and duration of bronchodilation action is also expected in the patients in obvious treatment of COPD upon the employment of the Carling's medicament.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 11-17 and 21-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-36 of **U.S. Patent No. 5,674,860** in view of Roberts et al. of record.

Instant claims are drawn to a method for reducing the frequency and intensity of COPD comprising administering to a patient suffering from COPD by inhalation comprising formoterol and budesonide.

The claims in the patent are drawn to the treatment of asthma and other inflammatory respiratory disorders which comprises adminsitering by inhalation to a host in need of such treatment comprising administration of formoterol and budesonide.

Therefore, the difference between the instant claims and the claims in the patent is the treatment of COPD versus the treatment of asthma.

It would have been obvious to one of ordinary skill in the art to employ the method of adminsitering combination of formoterol and budesonide for the treatment of COPD because the patent teaches that such combination is useful for the treatment of other inflammatory respiratory disorder including asthma and because Robert et al. teach that bronchodilators and inhaled steroids, as anti-asthma drugs, alone or together were prescribed to patients with respiratory disorders including asthma and COPD. (pages 1091, 1092). As such, the claims of the instant Application and the patented claims would have been obvious variations of the other to one of ordinary skill in the art.

Claims 9, 11-17 and 21-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-5, 9-12 and 15-19 of **U.S. Patent No. 5,972,919** in view of Roberts et al. of record.

Instant claims are drawn to a method for reducing the frequency and intensity of COPD comprising administering to a patient suffering from COPD by inhalation comprising formoterol and budesonide.

The claims in the patent are drawn to the treatment of asthma and other inflammatory respiratory disorders which comprises adminsitering by inhalation to a host in need of such treatment comprising administration of formoterol and budesonide.

Therefore, the difference between the instant claims and the claims in the patent is the treatment of COPD versus the treatment of asthma.

It would have been obvious to one of ordinary skill in the art to employ the method of adminsitering combination of formoterol and budesonide for the treatment of COPD because the patent teaches that such combination is useful for the treatment of other inflammatory respiratory disorder including asthma and because Robert et al. teach that bronchodilators and inhaled steroids, as anti-asthma drugs, alone or together were prescribed to patients with respiratory disorders including asthma and COPD. (pages 1091, 1092). As such, the claims of the instant Application and the patented claims would have been obvious variations of the other to one of ordinary skill in the art.

Claims 9, 11-17 and 21-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,9, 14-16 of **U.S. Patent No. 6,030,604** in view of Roberts et al. of record.

Instant claims are drawn to a method for reducing the frequency and intensity of COPD comprising administering to a patient suffering from COPD by inhalation comprising formoterol and budesonide.

The claims in the patent are drawn to the treatment of respiratory disorders which comprises adminsitering by inhalation to a host in need of such treatment comprising administration of formoterol and budesonide.

Therefore, the difference between the instant claims and the claims in the patent are the treatment of the specific respiratory disorder such as COPD.

It would have been obvious to one of ordinary skill in the art to employ the method of adminsitering combination of formoterol and budesonide for the treatment of COPD because the patent teaches that such combination is useful for the treatment of other inflammatory respiratory disorder including asthma and because Robert et al. teach that bronchodilators and inhaled steroids, as anti-asthma drugs, alone or together were prescribed to patients with respiratory disorders including asthma and COPD. (pages 1091, 1092). As such, the claims of the instant Application and the patented claims would have been obvious variations of the other to one of ordinary skill in the art.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
August 4, 2008